Adverse Drug Reaction Reporting System

Purpose and Scope

To improve medication safety by reducing and preventing adverse drug reactions, reducing severity and providing appropriate care when adverse drug reactions occur. To establish a mechanism for reporting, evaluating and tracking adverse drug reactions within Spring Grove Hospital Center

An adverse drug reaction is an unexpected, unintended, undesired, or excessive response to a drug that results in one or more of the following:

A. Requires discontinuing the drug
B. Requires changing the drug therapy
C. Requires modifying the dose (except minor adjustments)
D. Necessitates admission to an acute hospital or transfer to the medical surgical unit
E. Prolongs stay in a health care facility
F. Necessitates supportive treatment
G. Significantly complicates diagnosis
H. Negatively affects prognosis, or
I. Results in temporary or permanent harm, disability, or death

An adverse drug reaction (ADR) includes allergic reactions (immunologic hypersensitivity, the result of unusual sensitivity to a drug) and idiosyncratic reactions (abnormal susceptibility to a drug that is peculiar to the individual). A side effect is an expected, well-known reaction resulting in little or no change in patient management and is not considered an ADR.

Policy

All adverse drug reactions shall be reported concurrently by physicians, nurses, pharmacists, and other professional staff on the Adverse Drug Reaction reporting form or by telephoning the Pharmacy, on an ongoing basis.

Concurrent tracer drugs that are used to treat common ADR's (e.g. orders for immediate doses of antihistamines, epinephrine, and corticosteroids) should be reviewed.

Concurrent surveillance of events/triggers (e.g., patient falls, seizures, abnormal laboratory values) that may be the result of an ADR should be reported and reviewed. Adverse drug reaction monitoring will prospectively target high risk patient populations and high risk drugs.

Procedure

A. All adverse drug reactions and suspected adverse drug reactions shall be reported immediately to the physician on duty by the nurse.
B. The patient shall be monitored and treatment shall be given as directed by the physician.
C. The suspected drug reaction shall be documented in the patients Medical Record, e.g., nursing notes, progress notes.
D. The nurse, physician and/or other professional personnel who discover the ADR shall initiate the Adverse Drug Reaction Report Form. Alternately, adverse drug reactions may be reported by calling the pharmacist at extension 7156 or leaving a message on the ADR Hotline at extension 7117. The caller should provide the patient name/number, nursing unit, date of the reaction, type of reaction (dose and route), if known a brief description of the reaction and any symptoms.
E. All adverse drug reactions and suspected adverse drug reactions shall be reported to the pharmacy on the Adverse Drug Reaction Report Form or by phone within 24 hours.
F. The completed form shall be placed in the pickup box of the pharmacy or may be sent directly to the Pharmacy via mail or facsimile.
G. The Pharmacy designee will review the Adverse Drug Reaction Reporting Form and complete the Adverse Drug Reaction Evaluation Form.
H. The cause(s) of each suspected ADR are evaluated based on the patient's medical and medication histories, the circumstances of the adverse event, the results of dechallenge and rechallenge (if any), alternative etiologies and a literature review.
I. Adverse drug reactions will be analyzed for probability, severity and preventability.
J. Any medication order for immediate doses of diphenhydramine, epinephrine, loperamide, sodium polystyrene, naloxone, oral vancomycin or corticosteriods will be screened by the pharmacist to determine if they were initiated in response to an ADR, and if so, if an ADR Form was completed. If the medication order is in

response to an adverse drug reaction and no form has been received, one will be initiated.

K. All patient falls are screened to the determine if an ADR occurred and forwarded to the Pharmacy designee, if appropriate. If, after investigation, it is determined that the fall is an ADR, an ADR report form is completed and an evaluation completed.

L. If, after review by the pharmacy department, it is determined that an adverse drug reaction has occurred, the Pharmacy designee will forward their findings to Performance Improvement Department Steering Committee via a quarterly summary.

M. Prescribers will be notified by the Pharmacy Department when suspected ADR's are reviewed and rank as probable or definite. The prescriber will ensure that appropriate documentation and follow-up occur.

N. The Director of Pharmacy or a Pharmacy designee will report all unusual or rare adverse drug reactions to the Food and Drug Administration via letter, telephone or internet after consultation with the Pharmacy and Therapeutics Committee.

1. Med Watch
   The FDA Safety Information and Adverse Event Reporting Program
   Food and Drug Administration
   5600 Fishers Lane
   Rockville, MD 20852-9787
2. 1-800-FDA-1088

   1-800-FDA-0178 facsimile

   www.fda.gov/medwatch/report.htm

   1-800-822-7967 vaccine related adverse drug reactions

   https.//vaers.hhs.gov/esub/step1

O. All ADR reports are reviewed and evaluated by the Pharmacy and Therapeutics Committee. The committee will take action to reduce the incidence and severity of serious reactions. When trends are found in adverse drugs reactions, related systems and processes will be evaluated and recommendations made to improve the medication use process. Patient confidentiality shall be preserved.

P. Findings from the hospital's ADR monitoring and reporting program will be incorporated into ongoing performance improvement activities.

References:

American Society of Health-System Pharmacists. ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting Am J Health-Syst Pharm. 1995; 52: 417-9.

Comprehensive Accreditation Manual for Hospital: The Official Handbook

Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide 8th ed (Uselton, Kienle, and Murdaugh).

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